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WRIGHT MEDICAL TECHNOLOGY

A Wright Medical Group Company

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLVE® Ceramic Radial Head Implant.

Submitted By:	Wright Medical Technology, Inc.
Date:	February 3, 2003
Contact Person:	Jeanine H. Redden Regulatory Affairs Associate
Proprietary Name:	EVOLVE® Ceramic Radial Head Implant
Common Name:	RADIAL HEAD PROSTHESIS
Classification Name and Reference:	21 CFR 888.3170 Prosthesis, Elbow, Hemi-, Radial, Polymer – Class II
Device Product Code and Panel Code:	Orthopedics/87/ KWI

DEVICE INFORMATION

A. INTENDED USE

Use of the Modular Radial Head Implant may be considered for :

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  a. joint destruction and/or subluxation visible on x-ray; and/or
  b. resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

C. DEVICE DESCRIPTION

The EVOLVE® Ceramic Radial Head Implant is identical to the head component previously submitted and cleared under 510(k): K991915- EVOLVE® Modular Radial Head. The only difference between the two devices is the type of materials used to

manufacture the head components. The EVOLVE® Modular Radial Head system is approved with a CoCr head component, and a CoCr stem component. Wright Medical Technology is now adding a ceramic head component for use with the CoCr stem component previously cleared under the EVOLVE® Modular Radial Head (510(k): K991915).

The design features for both EVOLVE® radial head components are as follows:

- The proximal portion of the radial head will have a concave design to provide stability to the bearing surface and closely approximate the natural anatomy of the radial head and humeral-capitellum articulating surface.
- The sides of the head are designed with a radius of curvature that articulates with the proximal radial-ulnar joint and closely approximates the natural anatomy.
- The heads are interchangeable, since the interface has the same dimensions throughout the system.
- Heads are available in 2.0mm increments, ranging from 20.0mm to 28.0mm in diameter.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, type of interface, operating principles, shelf life, and design features of the EVOLVE® Ceramic Radial Head Implant are substantially equivalent to the head component covered under the EVOLVE® Modular Radial Head (510(k): K991915). The sterilization process and material used to manufacture the EVOLVE® Ceramic Radial Head Implant is substantially equivalent to the ORTHOSPHERE® Ceramic Spherical CMC Implant – 510(k): K960659. Additionally, the safety and effectiveness of the EVOLVE® Ceramic Radial Head Implant is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2003

Ms. Jeanine H. Redden
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Re: K030384
Trade/Device Name: EVOLVE® Ceramic Radial Head Implant
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: July 17, 2003
Received: July 18, 2003

Dear Ms. Redden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030384

WRIGHT MEDICAL TECHNOLOGY

A Wright Medical Group Company

EVOLVE® Ceramic Radial Head Implant

INDICATIONS STATEMENT

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- Revision following failed radial head arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K030384

Prescription Use Yes
(Per21 CFR 801.109)

OR

Over-The Counter Use No
(Optional Format 1-2-96)

5677 Airline Road Arlington, Tennessee 38002 901-867-9971